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10 UNITED STATES DISTRICT COURT
11 EASTERN DISTRICT OF WASHINGTON
12

13 JEREMY OLSEN,

14 Plaintiff,

15 vs.

16 XAVIER BECERRA, in his official
17 capacity as Secretary of the United States
18 Department of Health and Human
19 Services,
20

21 Defendant.
22

No. 2:21-cv-00326-SMJ

AMENDED ANSWER

23 The Defendant, Xavier Becerra, Secretary of Health and Human Services
24 (“Defendant”), through counsel, respectfully files this Amended Answer to Plaintiff’s
25 Complaint, ECF No. 1. The Secretary notes that, pursuant to 42 U.S.C. §
26 1395ff(b)(1)(A), the Court’s review in this action is based solely on the administrative
27 record, rather than the allegations of the parties in their respective pleadings.
28

PREFATORY STATEMENT

29 “It is often better to acknowledge an obvious mistake than defend it.” *Gate*
30 *Guard Servs., L.P. v. Perez*, 792 F.3d 554, 555 (5th Cir. 2015). Defendant
31

1 acknowledges that it made an obvious, unfortunate error in denying the Medicare claims
2 at issue in this case. Defendant has identified the root cause of the error, and taken
3 affirmative steps to ensure that Plaintiff will not be inconvenienced again.
4

5 Defendant also recently completed notice and comment rulemaking that
6 culminated in the publication of a final rule that classifies continuous glucose monitor
7 (CGM) devices like those used by Plaintiff as “durable medical equipment” under
8 Medicare Part B. *See* 86 Fed. Reg. 73860, 73896, (Dec. 28, 2021), available [here](#). This
9 new rule, which takes effect on February 28, 2022, effectively ensures that future CGM
10 claims submitted by Plaintiff and other similarly-situated Medicare claimants will be
11 covered.
12
13

14 Consistent with the admissions herein, Plaintiff is entitled to an administrative
15 remand to the Secretary of Health and Human Services for payment of his claims (which
16 payment the Secretary has already issued), and to an award of costs and attorney’s fees
17 under the Equal Access to Justice Act. Judgment should be entered in Plaintiff’s favor
18 to that effect.
19
20

21 I. INTRODUCTION

22 1. This paragraph consists of Plaintiff’s legal conclusions and
23 characterization of this lawsuit, to which no response is required.
24

25 2. Defendant admits that Plaintiff previously filed a lawsuit with respect to
26 claims for continuous glucose monitor (CGM) coverage in the matter of *Olsen v.*
27 *Becerra*, Case No. 20-cv-00374-SMJ (*Olsen I*). Defendant further admits that in *Olsen*
28

1 I the Plaintiff obtained a judgment ordering coverage of his CGM claims and that
2 attorney's fees were awarded to Plaintiff at market rates. The remainder of this
3 paragraph consists of Plaintiff's legal conclusions and characterization of this lawsuit,
4 to which no response is required. The Court is respectfully referred to its prior decision
5 for an accurate and complete statement of its contents.
6

7 3. Defendant admits that he erroneously rejected Plaintiff's CGM claims after
8 entry of the Court's decision in *Olsen I*. Defendant denies that he acted in bad faith.
9 Defendant affirmatively avers that he investigated why Plaintiff's claims were
10 erroneously denied, and determined that an employee of the Medicare Administrative
11 Contractor ("MAC") responsible for processing Plaintiff's claims failed to make a
12 manual adjustment to the submission code assigned to Plaintiff's claims in the MAC's
13 claims processing system that was needed to facilitate payment, as the employee had
14 been instructed to do following the decision in *Olsen I*. The MAC and its employees
15 have been re-educated to ensure that the required manual adjustment is made going
16 forward. The remainder of this paragraph consists of Plaintiff's legal conclusions and
17 characterization of this lawsuit, to which no response is required.
18
19
20
21

22 4. Defendant admits he erroneously rejected Plaintiff's CGM claims after
23 entry of the Court's decision in *Olsen I*. Defendant denies the remainder of the
24 allegations in this paragraph.
25

26 5. Defendant admits he erroneously rejected Plaintiff's CGM claims after
27 entry of the Court's decision in *Olsen I*. Defendant denies the remainder of the
28

1 allegations in this paragraph.

2 6. This paragraph consists of Plaintiff's characterization of this lawsuit and
3 his claims for relief. Defendant admits he erroneously rejected Plaintiff's CGM claims
4 after entry of the Court's decision in *Olsen I*. Defendant denies that the denial of those
5 CGM claims were a result of bad faith as opposed to mistake. Defendant admits Plaintiff
6 is entitled to have his CGM claims covered, and Defendant has, in fact, authorized
7 coverage for all of Plaintiff's submitted claims mentioned in the Complaint; those
8 claims have been paid as delineated in paragraph 76 herein. Defendant denies Plaintiff
9 is entitled to any other requested relief.
10

11 **II. JURISDICTION**

12
13
14 7. This paragraph consists of Plaintiff's legal conclusions regarding subject-
15 matter jurisdiction, to which no response is required.
16

17 8. This paragraph consists of Plaintiff's legal conclusions regarding subject-
18 matter jurisdiction, to which no response is required.
19

20 9. This paragraph consists of Plaintiff's legal conclusions regarding venue, to
21 which no response is required.

22 **III. PARTIES**

23 10. Admitted.

24 11. Admitted.
25

26 **IV. FACTUAL BACKGROUND**

27 12. Defendant admits that Plaintiff previously filed a lawsuit with respect to
28

1 claim for CGM coverage in *Olsen I* which contained Plaintiff's information and
2 allegations regarding diabetes and Plaintiff's characterization of the Medicare appeals
3 process.

4
5 **A. Durable Medical Equipment**

6 13. Defendant admits that 42 U.S.C. § 1395x(n) defines "durable medical
7 equipment." The remainder of this paragraph consists of Plaintiff's legal
8 characterization of Medicare coverage for "durable medical equipment" under 42
9 U.S.C. § 1395x(n), to which no response is required. The Court is respectfully referred
10 to the cited statutory provision for an accurate and complete statement of its contents.
11

12
13 14. Defendant admits that 42 U.S.C. § 1395x(n) includes "blood glucose
14 monitor" as an example of "durable medical equipment." The Court is respectfully
15 referred to the cited statutory provision for an accurate and complete statement of its
16 contents.
17

18 15. Defendant admits that the Secretary has issued regulations found at 42
19 C.F.R. § 414.202 relating to "durable medical equipment." The remainder of this
20 paragraph consists of Plaintiff's characterization the Secretary's regulations, to which
21 no response is required. The Court is respectfully referred to the cited regulation for an
22 accurate and complete statement of its contents.
23
24

25 16. Admitted that 42 C.F.R. § 414.202 contains the cited language, except with
26 respect to paragraph 16(b) of the Complaint, which is missing words from the
27 corresponding paragraph of 42 C.F.R. § 414.202. The complete second paragraph of
28

1 the definition of durable medical equipment in 42 C.F.R. § 414.202 states: “Effective
2 with respect to items classified as DME after January 1, 2012, has an expected life of at
3 least 3 years.” Defendant denies that this paragraph contains the full definition of
4 “durable medical equipment” that is contained in 42 C.F.R. § 414.202; the regulation
5 also specifies that durable medical equipment must be “furnished by a supplier or a
6 home health agency.” The Court is respectfully referred to the cited regulation for an
7 accurate and complete statement of its contents.
8
9

10 **B. CMS-1682-R**

11 17. This paragraph consists of a block quotation of a statutory provision.
12 Defendant admits 42 U.S.C. § 1395hh(a)(2) contains the quoted language without the
13 added emphasis. The Court is respectfully referred to the cited statutory provision for
14 an accurate and complete statement of its contents.
15
16

17 18. Defendant admits that 42 U.S.C. § 1395hh is applicable to the Secretary’s
18 “[a]uthority to prescribe regulations; ineffectiveness of substantive rules not
19 promulgated by regulation[.]” The remainder of this paragraph consists of Plaintiff’s
20 characterizations and legal conclusions regarding the statutory provision, to which no
21 response is required. The Court is respectfully referred to the cited statutory provision
22 for an accurate and complete statement of its contents.
23
24

25 19. Defendant admits that CMS Ruling 1682-R was issued on January 12,
26 2017. The phrase “final opinions and orders” appears in the prefatory statement of all
27 CMS Rulings. Denies the phrase “final opinion and order” appears in the substantive
28

1 body of CMS Ruling 1682-R. Plaintiffs' characterizations of CMS Ruling 1682-R are
2 denied except to admit that CMS Ruling 1682-R was not subject to notice and comment.
3 The Court is respectfully referred to the cited CMS Ruling.
4

5 20. Admitted that CMS Ruling 1682-R was issued on January 12, 2017, and
6 that the phrase "binding on all CMS components, on all Department of Health and
7 Human Services components that adjudicate matters under the jurisdiction of CMS, and
8 on the Social Security Administration" appears in CMS Ruling 1682-R, at page 1. The
9 Court is respectfully referred to the cited CMS Ruling for an accurate and complete
10 statement of its contents.
11
12

13 21. This paragraph contains Plaintiff's characterizations of CMS Ruling 1682-
14 R. The Court is respectfully referred to the cited CMS Ruling for an accurate and
15 complete statement of its contents.
16

17 22. Admitted that CMS Ruling 1682-R contains the quoted language.
18 Plaintiff's characterizations of CMS Ruling 1682-R are denied. The Court is
19 respectfully referred to the cited CMS Ruling for an accurate and complete statement
20 of its contents.
21

22 23. Plaintiff's characterizations of CMS Ruling 1682-R are denied. The Court
23 is respectfully referred to the cited CMS Ruling for an accurate and complete statement
24 of its contents.
25

26 24. Admitted that the Secretary denied coverage of certain continuous glucose
27 monitors on the grounds that they were not "primarily and customarily used to serve a
28

1 medical purpose” within the meaning of the Medicare regulations. The Secretary
2 otherwise lacks sufficient knowledge or information to form a belief about the truth of
3 these factual allegations. Pursuant to 42 U.S.C. § 1395ff(b)(1)(A), the Court’s review
4 in this action is based solely on the administrative record, rather than the allegations of
5 the parties in their respective pleadings; Defendant thus respectfully refers the Court to
6 the administrative record for an accurate and complete statement of its contents. To the
7 extent that these factual allegations are not reflected in the administrative record, they
8 are beyond the scope of the Court’s review in this case.
9

10
11 25. Denied.
12

13 26. Admitted that Local Coverage Determination L33822 was revised in
14 January 2017 to account for CMS Ruling 1682-R., and that this revision was not
15 preceded by a public comment period. The Court is respectfully referred to Local
16 Coverage Determination L33822 for an accurate and complete statement of its contents.
17

18 27. Admitted that Policy Article A52464 was revised on January 12, 2017, to
19 account for CMS Ruling 1682-R, and that this revision was not preceded by notice and
20 an opportunity to comment. The Court is respectfully referred to Policy Article A52464
21 for an accurate and complete statement of its contents.
22

23 28. This paragraph consists of Plaintiff’s characterization and legal
24 conclusions regarding CMS Ruling 1682-R, to which no response is required, but to the
25 extent a response is deemed required, denied. The Court is respectfully referred to CMS
26 Ruling 1682-R for an accurate and complete statement of its contents.
27
28

1 29. Admitted.

2 30. Admitted.

3 31. This paragraph consists of Plaintiff's characterizations and legal
4 conclusions regarding the treatment of continuous glucose monitors under Medicare
5 Part B, to which no response is required. To the extent a response is deemed required,
6 the Secretary lacks sufficient knowledge or information to form a belief about the truth
7 of this statement.
8
9

10 **C. Other Litigation Related to CGMs**

11 32. Denied as to the phrase "in general." Admitted that the Secretary denied
12 coverage of certain continuous glucose monitors on the grounds that they were not
13 "primarily and customarily used to serve a medical purpose" within the meaning of the
14 Medicare Part B regulations. Defendant denied coverage for non-therapeutic (*i.e.*,
15 "adjunctive") CGMs under the authority of CMS Ruling 1682-R; therapeutic (*i.e.*, "non-
16 adjunctive") CGMs were classified as "durable medical equipment" under CMS Ruling
17 1682-R, and have thus been covered. Denied to the extent the paragraph suggests that
18 the Secretary currently "contends" that CGMs are not primarily and customarily used
19 to serve a medical purpose.
20
21
22

23 33. Admitted that the Secretary previously adhered to the view that some
24 continuous glucose monitors are not covered as durable medical equipment. Denied to
25 the extent the statement suggests that the Secretary currently "contends" that a CGM is
26 excluded from coverage as precautionary. The second sentence in this paragraph
27
28

1 consists of Plaintiff's characterizations and legal conclusions regarding Local Coverage
2 Article A52464, which are denied. The Court is respectfully referred to Local Coverage
3 Article A52464 for an accurate and complete statement of its contents.
4

5 34. Admitted that several district courts have reviewed Medicare Part B
6 coverage determinations for continuous glucose monitors, including this Court in *Olsen*
7 *I.*
8

9 35. Admitted that some administrative law judges have concluded that certain
10 continuous glucose monitors are covered as durable medical equipment under the
11 Medicare statute and regulations. The remainder of this paragraph consists of plaintiff's
12 characterizations and legal conclusions regarding decisions by Medicare Administrative
13 Law Judges, to which no response is required. The Court is respectfully referred to the
14 cited decisions for accurate and complete statements of their contents.
15
16

17 36. Admitted that several district courts have reviewed Medicare Part B
18 coverage determinations for continuous glucose monitors, including this Court in *Olsen*
19 *I.* Admitted that certain district courts have concluded that continuous glucose monitors
20 are covered as durable medical equipment under the Medicare Part B statute and
21 regulations.
22

23 37. Admitted that certain district courts have concluded that continuous
24 glucose monitors are covered as durable medical equipment under the Medicare Part B
25 statute and regulations and ordered the Secretary to provide coverage. The remainder
26 of this paragraph consists of Plaintiff's characterizations and legal conclusions
27
28

1 regarding several district court decisions, to which no response is required. The Court
2 is respectfully referred to the cited decisions for an accurate and complete statement of
3 their contents.

4
5 38. Defendant admits the cited decision contains the quoted language. The
6 remainder of this paragraph consists of Plaintiff's characterizations and legal
7 conclusions regarding the district court's decision in *Whitcomb v. Azar*, to which no
8 response is required. The Court is respectfully referred to that decision for an accurate
9 and complete statement of its contents.
10

11 39. Defendant admits the four cited decisions contain the quoted language and
12 the plaintiffs in those actions were awarded attorney's fees. The remainder of this
13 paragraph consists of Plaintiff's characterizations and legal conclusions regarding
14 several district court decisions, to which no response is required. The Court is
15 respectfully referred the cited decisions for an accurate and complete statement of their
16 contents.
17

18
19 40. The Secretary denies the characterization of the cited administrative
20 decision, which speaks for itself. The Court is respectfully referred to the cited decision
21 for a full and complete statement of its contents.
22

23 **D. Facts Specific to Mr. Olsen**
24

25 41. Admitted.

26 42. Admitted.

27 43. Admitted.
28

1 44. Admitted.

2 45. Admitted.

3 46. Admitted.

4 47. Admitted.

5 48. Admitted.

6 49. Admitted.

7
8
9 **E. Prior Litigation Before This Court**

10 50. Admitted.

11 51. Admitted.

12 52. Admitted.

13 53. Admitted.

14 54. Admitted.

15
16
17 55. Defendant admits this Court granted judgment in Plaintiff's favor in *Olsen*
18 *I* (ECF No. 39). Defendant admits the cited decision contains the quoted language and
19 that this Court concluded that Plaintiff's CGM is covered as durable medical equipment
20 under the Medicare Part B statute and regulations. The Court is respectfully referred to
21 its prior decision for an accurate and complete statement of its contents.
22

23 56. Admits this Court's decision in *Olsen I* did not address the issuance of
24 CMS 1682-R. Denies Plaintiff's characterizations of the issuance of CMS 1682-R. The
25 Court is respectfully referred to its prior decision for an accurate and complete statement
26 of its contents.
27

1 57. Admitted.

2 58. Defendant admits this Court's Order awarding attorney's fees in *Olsen I*
3 (ECF No. 50) contains the quoted language. The remainder of this paragraph consists
4 of Plaintiff's characterizations of the Court's attorney fee ruling in *Olsen I* to which no
5 response is required. The Court is respectfully referred to its prior decision for an
6 accurate and complete statement of its contents.
7

8 59. Defendant denies the characterizations of the Court's attorney fee ruling in
9 *Olsen I* (ECF No. 50), which speaks for itself. The Court is respectfully referred to its
10 prior decision for an accurate and complete statement of its contents.
11

12 60. Admitted.

13
14 **V. The Claims at Issue in this Case**

15 61. Defendant admits that he erroneously rejected Plaintiff's CGM claims after
16 entry of the Court's decision in *Olsen I*. Defendant denies the remainder of the
17 allegations in this paragraph.
18

19 62. Defendant admits that he erroneously rejected Plaintiff's CGM claims after
20 entry of the Court's decision in *Olsen I*. Defendant denies the remainder of the
21 allegations in this paragraph.
22

23 **A. April 19 – July 18, 2019 Claim –**
24 **ALJ Appeal No. 3-8946502107/M-20-1269**

25 63. Admitted.

26 64. Defendant admits Plaintiff's April 19 – July 18, 2019 Claim was denied
27
28

1 by an ALJ decision dated January 31, 2020, prior to this Court's decision in *Olsen I.*
2 Defendant denies the remainder of the allegations in this paragraph.

3 65. Admitted.

4
5 66. Defendant admits that he erroneously rejected Plaintiff's CGM claims after
6 entry of the Court's decision in *Olsen I.* Defendant denies the remainder of the
7 allegations in this paragraph.

8
9 **B. March 10, 2021 Claim – ALJ Appeal No. 3-10205345873**

10 67. Admitted.

11 68. Admitted.

12
13 69. Defendant admits that he erroneously rejected Plaintiff's CGM claims after
14 entry of the Court's decision in *Olsen I.* Defendant denies the remainder of the
15 allegations in this paragraph.

16
17 70. Defendant admits that he erroneously rejected Plaintiff's CGM claims after
18 entry of the Court's decision in *Olsen I.* Defendant denies the remainder of the
19 allegations in this paragraph.

20
21 71. Admitted.

22 72. Defendant admits that he erroneously rejected Plaintiff's CGM claims after
23 entry of the Court's decision in *Olsen I.* Defendant denies the remainder of the
24 allegations in this paragraph.

25
26 73. Defendant lacks sufficient knowledge or information to admit or deny the
27 allegations in this paragraph, and therefore denies the same.

74. Admitted that Plaintiff sought expedited access to judicial review.

75. Admitted.

76. Defendant admits that a Medicare Summary Notice was issued to Plaintiff on or about October 1, 2021. Upon information and belief, fourteen (14) CGM claims from Plaintiff have been paid as indicated in the below chart, including thirteen (13) prior to October 1, 2021 and one (1) after October 1, 2021. The remainder of this paragraph consists of Plaintiff's characterizations of the MSN, to which no response is required.

CCN	Date of Service	Paid Date	Amount Paid
18137823767001	03/15/2018	07/22/2021	\$1,300.66
18172844803001	06/05/2018	07/15/2021	\$1,300.66
18283843973001	09/27/2018	07/15/2021	\$1,300.66
19008817632001	01/04/2019	07/15/2021	\$1,300.66
19112897095001	04/19/2019	07/15/2021	\$1,430.72
19210873889001	07/08/2019	07/15/2021	\$1,430.72
19296845388001	10/21/2019	07/15/2021	\$1,430.72
20031822855001	01/28/2020	07/15/2021	\$1,430.72
20139845927001	05/15/2020	07/15/2021	\$1,459.92
20230855617001	08/12/2020	07/15/2021	\$1,459.92
20330841967001	11/23/2020	07/15/2021	\$1,459.92
21076836253001	03/10/2021	07/15/2021	\$1,459.92
21204829122001	07/20/2021	08/03/2021	\$1,459.92
21288839976002	10/13/2021	12/27/2021	\$1,459.92

77. Admitted.

1 78. Defendant admits 42 C.F.R. § 405.352 governs adjustment of title XVIII
2 incorrect payments, including decreasing any payment to an individual under the Social
3 Security Act to which the individual is entitled. The remainder of the paragraph consists
4 of Plaintiff's characterizations and legal conclusions, to which no response is required.
5 The Court is respectfully referred to the cited regulation.
6

7 **1. October 30, 2021, Decision of ALJ Jason Earnhart**
8

9 79. Admitted that Plaintiff sought review by an administrative law judge. The
10 remainder of this paragraph consists of Plaintiff's characterization of that request, to
11 which no response is required.
12

13 80. Admitted.

14 81. Admitted. Defendant further admits that he erroneously rejected Plaintiff's
15 CGM claims after entry of the Court's decision in *Olsen I*.
16

17 82. Admitted that the administrative law judge issued a decision on Plaintiff's
18 claims. Defendant further admits that he erroneously rejected Plaintiff's CGM claims
19 after entry of the Court's decision in *Olsen I*. The remainder of this paragraph consists
20 of Plaintiff's characterization of that ALJ decision, to which no response is required.
21

22 83. Admitted that the administrative law judge issued a decision on Plaintiff's
23 claims. Defendant further admits that he erroneously rejected Plaintiff's CGM claims
24 after entry of the Court's decision in *Olsen I*. The remainder of this paragraph consists
25 of Plaintiff's characterization of that ALJ decision, to which no response is required.
26

27 84. Admitted that the administrative law judge issued a decision on Plaintiff's
28
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1 claims. Defendant admits that he erroneously rejected Plaintiff's CGM claims after
2 entry of the Court's decision in *Olsen I*. The remainder of this paragraph consists of
3 Plaintiff's characterization of that ALJ decision, to which no response is required.
4

5 85. Admitted that the administrative law judge issued a decision on Plaintiff's
6 claims denying coverage. Defendant further admits that he erroneously rejected
7 Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*. The remainder of
8 this paragraph consists of Plaintiff's characterization of that ALJ decision, to which no
9 response is required.
10

11 **2. November 2, 2021 Departmental Appeals Board Decision**
12

13 86. Admitted.

14 87. Admitted that Plaintiff sought review by the Departmental Appeals Board
15 (DAB). The remainder of this paragraph consists of Plaintiff's characterization of that
16 request, to which no response is required.
17

18 88. Admitted that the Departmental Appeals Board issued a decision denying
19 Plaintiff's request. The remainder of this paragraph consists of Plaintiff's
20 characterization of that DAB decision, to which no response is required.
21

22 89. Admitted that the Departmental Appeals Board issued a decision on
23 Plaintiff's request. The remainder of this paragraph consists of Plaintiff's
24 characterization of that DAB decision, to which no response is required.
25

26 90. Admitted that the Departmental Appeals Board issued a decision on
27 Plaintiff's request. The remainder of this paragraph consists of Plaintiff's
28

1 characterization of that DAB decision, to which no response is required.

2 VI. CAUSES OF ACTION

3 COUNT I

4
5 91. In this paragraph, Plaintiff repeats the paragraphs set forth above.
6 Defendant incorporates by reference his answers to all of the preceding paragraphs as
7 if fully set out herein.
8

9 92. This paragraph consists of a request for relief, to which no response is
10 required. To the extent that a response is deemed necessary, Defendant admits that he
11 erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen*
12
13 *I.* Defendant avers that he has since made appropriate payment to Plaintiff for the claims
14 that are the subject of this case. Defendant consents to administrative remand of this
15 matter for payment of any pending CGM claims from Plaintiff properly before this
16 Court. Defendant further affirmatively avers that on December 28, 2021, through
17 notice-and-comment rulemaking, the Centers for Medicare & Medicaid Services, U.S.
18 Department of Health and Human Services, issued a final rule entitled, *Medicare*
19 *Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*
20 *(DMEPOS) Policy Issues, and Level II of the Healthcare Common Procedure Coding*
21 *System (HCPCS); DME Interim Pricing in the CARES Act; Durable Medical*
22 *Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates*
23 *To Provide Relief in Rural Areas and Non-Contiguous Areas*, 86 Fed. Reg. 73,860,
24 73,860–73,911 (Dec. 28, 2021) (the "Final Rule"). The Final Rule effectively replaces
25
26
27
28

1 CMS 1682-R, which forms the basis of Plaintiff's claims in this case, is effective as of
2 February 28, 2022. The recently issued Final Rule makes clear that "claims submitted
3 for CGM sensors and transmitters used with insulin pumps are being denied
4 inappropriately based on CMS-1682-R" because that "Ruling only addressed the
5 classification of CGM receivers as DME and did not address coverage of CGM sensors
6 and transmitters used with insulin pumps." 86 Fed. Reg. at 73,898. Further, the Final
7 Rule states that the Secretary "now believe[s] that ... glucose sensors and transmitters
8 used with insulin pumps ... are primarily and customarily used to serve a medical
9 purpose." *Id.* at 73,899.

10
11
12
13 93. This paragraph consists of a request for relief, to which no response is
14 required. To the extent that a response is deemed necessary, Defendant refers to its
15 answer in response to Paragraph 92. Defendant admits that he erroneously rejected
16 Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has
17 since made appropriate payment to Plaintiff for the claims that are the subject of this
18 case, consents to administrative remand of this matter for payment of any pending CGM
19 claims from Plaintiff properly before this Court, and notes that the Final Rule effective
20 February 28, 2022, resolves the classification as DME of future CGM claims from
21 Plaintiff and other similarly-situated CGM claimants.

22 COUNT II

23
24
25
26 94. In this paragraph, Plaintiff repeats the paragraphs set forth above.
27 Defendant incorporates by reference his answers to all of the preceding paragraphs as

1 if fully set out herein.

2 95. This paragraph consists of a request for relief, to which no response is
3 required. To the extent that a response is deemed necessary, Defendant refers to its
4 answer in response to Paragraph 92. Defendant admits that he erroneously rejected
5 Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has
6 since made appropriate payment to Plaintiff for the claims that are the subject of this
7 case, consents to administrative remand of this matter for payment of any pending CGM
8 claims from Plaintiff properly before this Court, and notes that the Final Rule effective
9 February 28, 2022, resolves the classification as DME of future CGM claims from
10 Plaintiff.
11

12 96. This paragraph consists of a request for relief, to which no response is
13 required. To the extent that a response is deemed necessary, Defendant refers to its
14 answer in response to Paragraph 92. Defendant admits that he erroneously rejected
15 Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has
16 since made appropriate payment to Plaintiff for the claims that are the subject of this
17 case, consents to administrative remand of this matter for payment of any pending CGM
18 claims from Plaintiff properly before this Court, and notes that the Final Rule effective
19 February 28, 2022, resolves the classification as DME of future CGM claims from
20 Plaintiff.
21

22 **COUNT III**

23 97. In this paragraph, Plaintiff repeats the paragraphs set forth above.
24
25

1 Defendant incorporates by reference his answers to all of the preceding paragraphs as
2 if fully set out herein.

3 98. This paragraph consists of a request for relief, to which no response is
4 required. To the extent that a response is deemed necessary, Defendant refers to its
5 answer in response to Paragraph 92. Defendant admits that he erroneously rejected
6 Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has
7 since made appropriate payment to Plaintiff for the claims that are the subject of this
8 case, consents to administrative remand of this matter for payment of any pending CGM
9 claims from Plaintiff properly before this Court, and notes that the Final Rule effective
10 February 28, 2022, resolves the classification as DME of future CGM claims from
11 Plaintiff.
12

13 99. This paragraph consists of a request for relief, to which no response is
14 required. To the extent that a response is deemed necessary, Defendant refers to its
15 answer in response to Paragraph 92. Defendant admits that he erroneously rejected
16 Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has
17 since made appropriate payment to Plaintiff for the claims that are the subject of this
18 case, consents to administrative remand of this matter for payment of any pending CGM
19 claims from Plaintiff properly before this Court, and notes that the Final Rule effective
20 February 28, 2022, resolves the classification as DME of future CGM claims from
21 Plaintiff.
22

23
24
25
26
27
28 //

COUNT IV

100. In this paragraph, Plaintiff repeats the paragraphs set forth above. Defendant incorporates by reference his answers to all of the preceding paragraphs as if fully set out herein.

101. This paragraph consists of a request for relief, to which no response is required. To the extent that a response is deemed necessary, Defendant refers to its answer in response to Paragraph 92. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has since made appropriate payment to Plaintiff for the claims that are the subject of this case, consents to administrative remand of this matter for payment of any pending CGM claims from Plaintiff properly before this Court, and notes that the Final Rule effective February 28, 2022, resolves the classification as DME of future CGM claims from Plaintiff.

102. This paragraph consists of a request for relief, to which no response is required. To the extent that a response is deemed necessary, Defendant refers to its answer in response to Paragraph 92. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has since made appropriate payment to Plaintiff for the claims that are the subject of this case, consents to administrative remand of this matter for payment of any pending CGM claims from Plaintiff properly before this Court, and notes that the Final Rule effective February 28, 2022, resolves the classification as DME of future CGM claims from

1 Plaintiff.

2 **COUNT V**

3 103. In this paragraph, Plaintiff repeats the paragraphs set forth above.
4 Defendant incorporates by reference his answers to all of the preceding paragraphs as
5 if fully set out herein.
6

7 104. This paragraph consists of a request for relief, to which no response is
8 required. To the extent that a response is deemed necessary, Defendant refers to its
9 answer in response to Paragraph 92. Defendant admits that he erroneously rejected
10 Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has
11 since made appropriate payment to Plaintiff for the claims that are the subject of this
12 case, consents to administrative remand of this matter for payment of any pending CGM
13 claims from Plaintiff properly before this Court, and notes that the Final Rule effective
14 February 28, 2022, resolves the classification as DME of future CGM claims from
15 Plaintiff.
16

17 105. This paragraph consists of a request for relief, to which no response is
18 required. To the extent that a response is deemed necessary, Defendant refers to its
19 answer in response to Paragraph 92. Defendant admits that he erroneously rejected
20 Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has
21 since made appropriate payment to Plaintiff for the claims that are the subject of this
22 case, consents to administrative remand of this matter for payment of any pending CGM
23 claims from Plaintiff properly before this Court, and notes that the Final Rule effective
24
25
26
27
28

1 February 28, 2022, resolves the classification as DME of future CGM claims from
2 Plaintiff.

3
4 **COUNT VI**

5 106. In this paragraph, Plaintiff repeats the paragraphs set forth above.
6 Defendant incorporates by reference his answers to all of the preceding paragraphs as
7 if fully set out herein.
8

9 107. This paragraph consists of a legal conclusion to which no response is
10 required.

11 108. This paragraph consists of a legal conclusion to which no response is
12 required.
13

14 109. Denied.

15 110. This paragraph consists of a legal conclusion to which no response is
16 required.
17

18 111. Denied.

19 112. Denied.
20

21 **VII. PRAYER FOR RELIEF**

22 The remaining paragraphs of the complaint contain Plaintiff's requested relief, to
23 which no response is required. To the extent that a response is deemed necessary,
24 Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the
25 Court's decision in *Olsen I*, avers that he has since made appropriate payment to
26 Plaintiff for the claims that are the subject of this case, consents to administrative
27
28

1 remand of this matter for payment of any pending CGM claims from Plaintiff properly
2 before this Court, and notes that the Final Rule effective February 28, 2022, resolves
3 the classification as DME of future CGM claims from Plaintiff. Finally, Defendant
4 admits Plaintiff is entitled to costs and reasonable attorneys' fees in an amount to be
5 determined by this Court. With respect to any remaining requests for relief, Defendant
6 denies that Plaintiff is entitled to any other relief.
7

8
9 **AFFIRMATIVE DEFENSES**

10 1. To the extent Plaintiff is seeking an injunction requiring Defendant to grant
11 coverage for CGM claims, the Court lacks jurisdiction to grant such relief.
12

13 2. To the extent Plaintiff is seeking appointment of a special master to make
14 coverage decisions on CGM claims, the Court lacks jurisdiction to grant such relief.
15

16 RESPECTFULLY SUBMITTED: February 17, 2022.

17 Vanessa R. Waldref
18 United States Attorney

19 s/Brian M. Donovan
20 Brian M. Donovan
21 John T. Drake
22 Assistant United States Attorneys
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CERTIFICATE OF SERVICE

I hereby certify that on February 17, 2022, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

Roger M. Townsend: rtownsend@bjtlegal.com

James Pistorino james@parrishlaw.com

And to the following non CM/ECF participants: N/A

s/ Brian M. Donovan
Assistant United States Attorney